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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,165	03/01/2000	Vladimir Andrei Koulchin		4746

7590 12/11/2003

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,165	KOULCHIN ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,23-25,28-33,35-42 and 53-59* is/are pending in the application.

4a) Of the above claim(s) *1 and 2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25,28-33,35-42 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination

1. This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for an entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Amendment Entry

2. The amendment filed August 23, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 23-25, 28, 30-31, 33, 35-38, and 40-42 have been amended. Claims 1-2 have been withdrawn. Claims 3-22, 26-27,

34, 43-52 have been cancelled. Claims 53-59 are newly added. Claims 23-25, 28-33, 35-42 and 53-59 are under consideration in the office action.

3. A complete reply to the rejection must include cancellation of nonelected claims 1-2 or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 23-25, 28-33, 35-42 and 53-59 of this application.

Applicant asserts that the prior applications do not disclose that entirety of the instant invention but rather applicants are claiming the generic methodology disclosed in the prior applications therefore at least partial priority should be granted.

However, there was no conception of a method to detect the presence or concentration of any bacterial species as now claimed. The instant claims comprise using undisclosed antigens in the method of detection, yet there is no support for such disclosure in this application or the prior applications. The prior applications only detect specific bacterial species such as *Legionella* and *S. pnuemoniae* that according to the disclosures require specific extraction procedures; there is no teaching of generic procedures for all bacterial species.

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention,. must be described in such details, including

proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications or be found to adequately supportive of priority claims. *In re Glass*, 492 F.2d 1228, 181 USPQ 31(CCPA 1974).

Applicants' assertions to the contrary are not sufficient to overcome the fact that priority cannot be granted to any of 09/139,720, 09/156,486, 09/397,110 and 09/458,998 for the broad generic methodology now claimed in 09/518,165 since what is now claimed was not been previously recited in the prior applications.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date in order to obtain priority. None of the parent applications, for which priority is claimed 09/139,720, 09/156,486, 09/397,110 and 09/458,998 teach a method for detecting both gram-negative and gram-positive bacteria and associated devices. There is no teaching of a method wherein all species of bacteria are assayed for. There was no conception of a method to detect the

presence or concentration of any bacterial species rather the prior applications only detect specific bacterial species. Applicants' argument that the prior applications teach segments of generic concepts is not adequate to claim priority. Therefore, priority cannot be granted to 09/139,720, 09/156,486, 09/397,110 and 09/458,998 since what is now claimed, has not been previously recited in the other applications. Thus

Withdrawal of Objections and Rejections

5. The following rejection have been withdrawn in view of applicants' amendments:

a)

Response to Arguments

Applicant's arguments filed August 23, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The enablement rejection of claims 23-25, 28-33, 35-42 and 53-59 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The rejection was on the grounds that is no teaching of a method for detection that encompasses combining all the separate examples into one hybrid method.

New independent claim 53 is drawn to a method for detecting the presence in a fluid sample of a target carbohydrate antigen comprising obtaining a culture of a known bacterial species; coupling an essentially protein-free embodiment of a target carbohydrate antigen to a chromatographic affinity gel; passing polyclonal antibodies raised in a mammal against said bacteria or target carbohydrate antigen in crude form over the affinity gel and eluting there from antibodies with enhanced specificity to the target carbohydrate antigen; and conducting an assay upon the liquid sample comprising contacting the liquid sample with a detection agent comprising antibodies with enhanced specificity and detecting the presence in the sample the crude target carbohydrate antigen.

New independent claim 55 is drawn to an article of manufacture, an ICT device, comprising a housing equipped with a view window; a sample receiving zone; a first zone; and a second zone.

The specification teaches that some gram-negative bacteria possess lipopolysaccharide or lipo-polycarbohydrate antigens while gram-positive bacteria generally posses lipo-teichoic acid or teichoic acid (page 2). Therefore the instant invention is limited to testing on bacteria that possess either the lipopolysaccharide, lipo-polycarbohydrate, lipo-teichoic acid or teichoic acid antigens. Example 1 is drawn to culturing the target carbohydrate antigen of *Haemophilus influenzae* type b; Example 2 is drawn to purification of that carbohydrate antigen; Example 3 is drawn to preparation

of an affinity column; Example 4 is drawn to purification of those antibodies; Example 5 is drawn to an ICT assay for *H. influenzae* type b; and Example 6 is drawn to cross-reactivity/compatibility of antigen specific *H. influenzae* antibodies. There is no teaching of a generic method that can be used with any species of bacteria.

However the instant specification fails to provide any experiments that show the combination of purifying any carbohydrate antigens from all types of bacteria and conducting an assay as one method for detecting the presence of a carbohydrate antigen. First the art purification is highly unpredictable and the instant specification fails to provide any information that any bacterial carbohydrate antigens could be purified and detected in the claimed generic manner. Moreover, applicants' specification is not a general outline of purifying carbohydrate antigens and elucidating antibodies that bind contrary to applicants' assertion. The specification fails to set forth purification guidance specific for different types of bacteria. For instance, the instant specification at page 14 teaches purification of a *H. influenzae* type b carbohydrate antigen steps, including an incubation step, sonication step, repeated precipitation and centrifugation steps, lyophilization, subjected to Lowry assay for proteins and tested for carbohydrate by phenol-sulfuric acid method. It is well known in the art that specific bacterial species require specific extraction methods, yet the claims do not take this into consideration. The generically claimed method of detection also fails to disclose appropriate purification steps for any species of bacteria. The instant claims fail to recite any specific method steps necessary to detect these crude carbohydrate antigens of any type of bacteria. Applicants have failed to disclose antibodies with enhanced specificity to any

and all species of bacteria. The specification fails to even take into account the different eluding reagents necessary to elute the many different antibodies used in the chromatography affinity gel aspect of the assay.

There is no support in the specification for obtaining an essentially protein-free carbohydrate antigen in the manner claimed for any type of bacterial species. Furthermore, the claims are not enabled for conducting as assay by contacting liquid sample with a detection agent that essentially comprises labeled purified antigen-specific antibodies. Currently the claims do not requires a particular type of bacteria; and in view of the method for detection of any type of bacteria, the specification fails to teach how to produce a purified antigen specific antibody that binds to an essentially protein free carbohydrate bacterial antigen.

Applicants assert that the invention lies in the purified antibodies which exhibit greatly enhanced specificity toward the target carbohydrate antigen in the sample enable rapid diagnosis of bacterially caused disease. However the issue at hand is that the specification fails to enable the entire method of detection including the specific steps. Neither the specification nor the claims have actually identified these antibodies that enhanced specificity to each type of bacteria. Applicants have failed to make antibodies that can target any bacterial carbohydrate antigen in the sample. Applicants have failed to teach a method that can diagnosis a disease; at best the instant method can detect the presence of a target carbohydrate antigen. The method cannot tell what type of disease the bacteria caused. Moreover, one would have to know at the outset, what type of bacteria a person was infected with because that person would then have

to use polyclonal antibodies raised to that target carbohydrate antigen to run in the gel. Therefore, applicants' argument is completely unpersuasive.

There is no teaching of a method for detection that encompasses combining all the separate examples into one hybrid method. Applicants assert that the same methodology can be used with either gram-negative or gram-positive bacteria, therefore the methodology is enabled. However, the claims are drawn to a method for detecting the presence in a fluid sample of a target carbohydrate antigen. The method requires knowing what the target carbohydrate antigen is and than passing and eluting polyclonal antibodies. The specification and claims fail to enable one of skilled in the art how to distinguish between the antibodies that have the enhanced specificity the antibodies that fail to have the enhanced specificity.

Applicants claim that the only patentable aspect of the claims is the enhanced antibodies bodies, however applicants have failed to enabled one skilled in the art to make and use the invention because there appears to be no conception of a method for detecting the presence of a carbohydrate antigen characteristic of a species or serogroup of a species of bacteria.

Applicants argue that the reference to Critical Synergy: The Biotechnology Industry and Intellectual Property Protection, Presentation of the intellectual Property Committee of the Biotechnology Industry Organization at the October 17, 1994, Hearing of the U.S. Patent and trademark Office, San Diego, CA, published by the Biotechnology Industry Organization, Washington, D.C. pages 100-107 was taken out of

context because is was geared to specific areas of technology, which applicant deems, without any evidence to be non-inclusive of immunoassays, antigens and antibodies. Applicants' inability to obtain the entire document is unfortunate despite adequate reference being made and supplied by the examiner.

Applicants' question how the hybrid method relates to the patentability and that the examples are broken up to increase clarity. However it is the examiner's position that since there is no hybrid method which encompasses the broad generic claims, yet such a method is necessary in order to achieve the functional limitation of an essentially protein-free carbohydrate antigen and purified antigen specific antibodies, the disclosure needs to teach purification procedures specific to individual species of gram negative and gram positive bacteria, or prove that any bacteria can be purified by the same generic methods. The disclosure does not teach how to achieve the instantly claimed property or assurance of particular results which would be obtained if certain direction were pursued producing an essentially protein free carbohydrate bacterial antigen is a highly empirical process yet the specification fails to teach the critical or key characteristics of the bacterial carbohydrate antigens; moreover, the specification needs to teach particular combination of reagents.

There are an infinite number of combinations of possible columns, gradients, gels, centrifugations, in combination with appropriate buffers of varying pH, salt, etc., however, the specification fails to supply an essentially protein-free carbohydrate antigen from any bacteria. In absence of further guidance from applicants' as to how to purify the antigens to a degree which is an essentially protein-free carbohydrate

antigen, and in view of the unpredictability and complexity in the art, it would require undue experimentation on the part of a skilled artisan to discover the key and critical characteristics of the bacteria which allow one skilled in the art to choose from the plethora of bacterial purification procedures in order to achieve an essentially protein-free carbohydrate antigen. The claims are further drawn to conducting an assay which comprises detecting crude carbohydrate antigen of any species of bacteria by contacting the liquid sample with a detection agent which essentially comprises labeled purified antigen-specific antibodies, however the specification recites requiring the addition of "reagent A", TWEEN 20 ™, sodium azide, sodium dodecydl sulfate in sodium citrate phosphate buffer to produce the crude carbohydrate antigen, however the instant claims fail to recite adding the appropriate reagents. Thus, it is unclear that one of skill in the art could follow these general guidelines and achieve purification of an essentially protein-free carbohydrate antigen.

Applicants assert that the application does not suggest that a carbohydrate antigen characteristic of both a gram-negative and gram-positive bacterial species at the same time, and that the specification does not to target both simultaneously. However, the instant claims fail to distinguish between detecting gram negative and positive bacteria by separate method steps. The broad and generic claims encompass detecting a species or serogroup of any bacteria, thereby including detecting multiple species in the manner claimed. If applicants do not intend for the claims to encompass such than applicant should narrowly tailor the claims to only encompass what is taught

and supported by the instant specification. Applicants' statement that specific sample types perform extraction on some bacteria only bolsters the examiner's position that broad generic techniques cannot apply to all types of bacteria in any type of sample.

Absent clear demonstration of the detection of any bacterial carbohydrate antigen, the purification and detection methods could not used in any well-established manner. In absence of further guidance from applicants, the skilled artisan would have to discover what the appropriate substrate is and the conditions under which the bacteria could be extracted. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. The need for non-routine experimentation demonstrates the specification is not enabled for the asserted use or well-established use for detection of bacterial carbohydrate antigens. Accordingly, the specification is not enabled for using the alleged method and device in any manner disclosed and the rejection is maintained.

The use of any carbohydrate antigen would not predictably result in a detectable crude antigen. The specification does not provide guidance on how to produce said derivatives from the crude antigen. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which derivatives of the acids will enable the detection of the crude antigen in the recited method. Accordingly, one of skill in the art would be required to perform undue experimentation to detect the crude antigen. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Claim 36 recite esters of either lipoteichoic acid or teichoic acid, however the there appears to be no support for the ester of either in the specification, thus the claims are not enabled for esters of either acid. Applicants' arguments to the contrary are not sufficient to overcome the rejection. The specification provides no guidance as to what esters of either lipoteichoic acid or teichoic acid can be produced. The claims broadly recite said esters, but fails to disclose the production of specific esters. Thus the recitation of esters of either lipoteichoic acid or teichoic acid is not enabled by the specification. The substitution of any esters would not predictably result in a detectable crude antigen. The specification does not provide guidance on how to produce esters from the crude antigen. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which esters of the acid will enable the detection of the crude antigen in the recited method and device. Accordingly, one of skill in the art would be required to perform undue experimentation to use esters of either lipoteichoic acid or teichoic acid to detect the crude antigen. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Therefore applicants' arguments are not persuasive and the rejection is maintained.

7. The new matter rejection of claim 24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention is maintained for reasons already of record.

Claim 24 recites derivative of either lipoteichoic acid or teichoic acid however, the appears to be no support in the specification for the derivatives of either; however there appears to be no support for the ester of either in the specification. Claims 33 and 42 are drawn to detecting *Haemophilus influenzae* type b, however there appears to be no support in the specification for using the claimed purification steps to specifically purify *Haemophilus* antigen. Applicants have failed to adequately address the rejection, therefore the rejection is maintained.

8. The rejection of claims 23-25, 28-33, 35-42 and 53-59 are rejected under 35 U.S.C. 112, second paragraph, is maintained for reasons already of record.

Claims 53 is unclear because it recites passing polyclonal antibodies over the chromatographic affinity gel and eluting there from antibodies with enhanced specificity to the target carbohydrate antigen however it is unclear where the how one can determine which antibodies are now enhanced. What is the basis of the enhancement? How does define which antibodies are enhanced? Moreover, the antibodies must be obtained before they are passed through the column. Clarification is requested.

9. Claim 24 still recites derivative of either (lipoteichoic acid or teichoic acid). The specification is silent concerning a definition of what constitutes the metes and bounds of such derivatives of either lipoteichoic acid or teichoic acid. Therefore, the claim is

unclear and indefinite as to what is encompassed by the phrase "derivative of either". It is unclear how to define the derivative when there appears to be no support in the specification for the derivatives of either. Thus the metes and bounds of the claim cannot be ascertained.

10. Claim 36 still recites esters of either (lipoteichoic acid and teichoic acid) however this recitation makes the claim indefinite. The specification is silent concerning a definition of what constitutes the metes and bounds of such derivatives of either lipoteichoic acid or teichoic acid. Therefore, the claim is unclear and indefinite as to what is encompassed by the phrase "derivative of either". It is unclear how to define the derivative when there appears to be no support in the specification for the derivatives of either. Thus the metes and bounds of the claim cannot be ascertained.

Double Patenting

11. Applicants' statement that a terminal disclaimer is acknowledged. However the rejection will be maintained until such time.

The rejection of claims 23-25, 28-33 and 43-59 of this application conflict with claims 10-14 and 25-29 of Application No. 09/458,998 is maintained.

The provisional rejection of claims 23 and 25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14 and 25-29 of copending Application No. 09/458,998 is maintained.

The provisional rejection of claims 24, 26-32, 34-40, and 43-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-36, 41, 43-46, and 50-54 of copending Application No. 09/397,110 is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The rejection of claims 55-59 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., (US Patent 5,415,994) in view of Barthe (J. Clin. Micro. 1988) is maintained.

Applicant argues that there is no evidence that the prior art device was used to detect either *Legionella* or *Haemophilus*. However the claims are not limited to anything but the detection of a carbohydrate antigen using a device with the claimed components.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Imrich et al. (US Patent 5,415,994) teach devices, methods and kits for detecting analytes in biological sample where prior to detection, extraction can occur. It would have been prima facie obvious to modify the

immunochromatographic device for the detection of an antigen of a species of bacteria, which comprises a first and second zone and method for detecting the crude antigen as taught by Imrich et al., to include the antibody of Barthe et al., because Barthe et al., antibody recognizes several crude carbohydrate antigens from *Legionella*. One would have a reasonable expectation of success by incorporating the an antibody with recognizes a common epitope found on Legionella, into the device and method of Imrich who already teach using the antibodies to bind and label the bacterial antigens to detect there presence. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent antibody in the labeling and capturing technique of Imrich et al., since only the expected results would have been obtained; thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the monoclonal antibodies ability to recognize several *Legionella* serogroups.

Contrary to applicants' argument that the Barthe et al., antibody will not detect a carbohydrate antigen; applicant is pointed to applicants definition of a carbohydrate antigen. The carbohydrate antigens include lipopolysaccharides. The antibody of Barthe et al., detects the lipopolysaccharide carbohydrate antigen. Therefore, the antibody of Barthe et al., meets the limitations of the claims.

Claims 54-59 are drawn to an ICT device, whiles claim 53 is drawn to a method of detection using the device, however the claims recite the use of antigen-specific antibodies. The claims are drawn to a product by process, however the process for creating an essentially free protein carbohydrate antigen do not create provide for a

materially different antibody. The antibody of Barthe et al., will also bind to the crude carbohydrate antigen. Thus, absent evidence to the contrary, the antibody of Barthe et al., meets the limitations of the claimed device, by being capable of binding to crude carbohydrate antigens. Applicants' claims are drawn to device, thus the source of immunoglobulins also known as antibodies, do not provide a structural difference between the device of Imrich et al., in view of Barthe et al. Moreover, there are no structural difference between the claimed antibody and device and the antibody and device of the recited prior art. A structural difference needs to exist in order to patentably distinguish the claimed invention from the prior art; the prior art antibody and device are capable of performing just like the instantly claimed device, thus they meet the claimed limitations.

Applicant asserts that the novelty lies in the affinity purified polyclonal antibodies; however the claims are not directed to the antibody. Rather the claims are directed to the well-known device. The prior art teaches the device, therefore the prior art meets the limitations of the claim. The claims are not drawn to a specific affinity purified polyclonal antibody, therefore applicants arguments are not persuasive.

Because the claims are drawn to a device, the structures of the device are at issue. The prior art references teach all of the structural aspects of the claimed invention. In response to applicant's argument a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Therefore, applicants' arguments are not persuasive and the rejection is maintained.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
December 2, 2003

MARK NAVARRO
PRIMARY EXAMINER